King, Valerie A.

From: Oey, Jan
Sent: Wednesday, February 19, 2003 12:28 PM
To: King, Valerie A.; Kinser, Robin D.
Subject: FW: EHCJLI/04/03 Menthol

Sensitivity: Confidential

[redacted] AA04271_D2_19FEB0 3_Philip Morr...

[redacted] AA04271_19FEB03_A TTACHMENTS_Ph...

For your review,

Jan

-----Original Message-----
From: Michael Szwanek (402)437-4880 [mailto:Michael.Szwanek@mdsps.com]
Sent: Wednesday, February 19, 2003 11:46 AM
To: jan.oey@pmusa.com; Hans-Juergen.Roethig@pmusa.com; martin.unverdorben@pmusa.com; qiwei.liang@pmusa.com; bettie.l.nelson@pmusa.com; paul.mendes@pmusa.com
Cc: Paul Johnson; Megan McCrory; Kimberly Prchal; Steve Hambek; Robert Earl
Subject: EHCJLI/04/03 Menthol
Sensitivity: Confidential

All,

Attached is draft two protocol and selected attachments dated Feb 19, 2003 for the upcoming 10-day Menthol study for your review. I have incorporated all changes discussed since the original first draft that was released on Jan 31, 2003. I would appreciate a thorough review as many changes have been made since the first draft including the addition of another group which affects all sections of the protocol including objectives and stats. I assume that you will also need to have the Philip Morris legal team review as well.

There is a high possibility that the IRB date for this study may change from March 11 to March 7. If this happens, then I'll need all documents (protocol, attachments, ICF) final and ready for submission by Friday, Feb 28, 2003. We will begin modifying the ICF immediately and have for you before the end of the week.

Thanks,

Michael F. Szwanek, Pharm D., MBA
Section Head, Protocol Development and ICFs
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